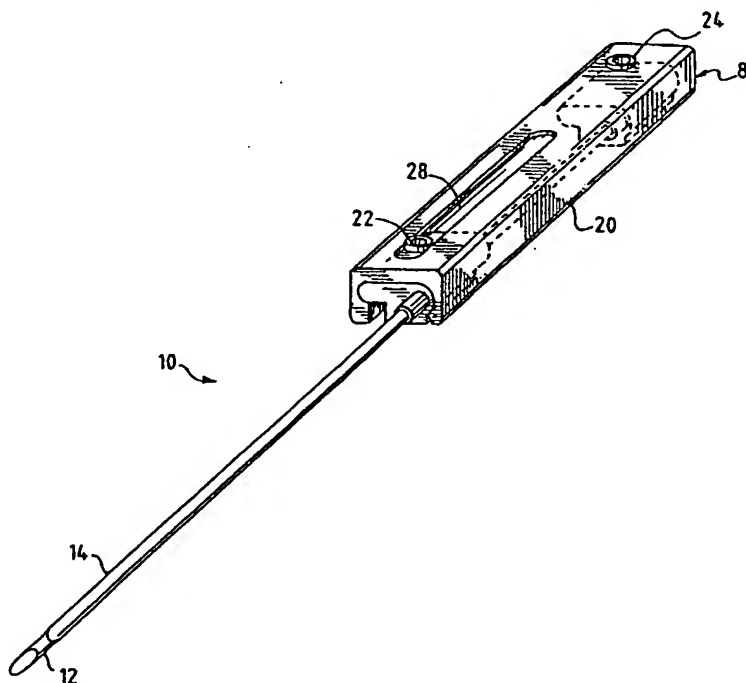




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷: A61B 10/00	A2	(11) International Publication Number: WO 00/59378 (43) International Publication Date: 12 October 2000 (12.10.00)
(21) International Application Number: PCT/IB99/02131 (22) International Filing Date: 13 July 1999 (13.07.99) (30) Priority Data: 09/114,509 13 July 1998 (13.07.98) US (71) Applicant: MEDICAL DEVICE TECHNOLOGIES, INC. [US/US]; 4445-310 S.W. 35th Terrace, Gainesville, FL 32608 (US). (72) Inventor: TERWILLIGER, Richard; 332 Ute Lane South, Estes Park, CO 80517 (US). (74) Agents: TANG, Wayne, L. et al.; Mayer Brown & Platt, P.O. Box 2828, Chicago, IL 60690-2828 (US).		(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: BIOPSY NEEDLE AND SURGICAL INSTRUMENT		
(57) Abstract		
<p>The present invention includes a biopsy needle for use in a biopsy gun or as surgical instrument, capable of taking multiple samples, and a guiding needle holder for holding a biopsy needle. The biopsy needle includes an inner needle, also called a stylet, and an outer needle, also called a cannula, and a guiding needle holder. The stylet has a recess in the vicinity of its distal end which receives the tissue sample. The guiding needle holder includes an integrated spacer, and first and second connecting elements. The first connecting element holds the proximal end of the cannula and is displaceably attached along the length of the integrated spacer. The second connecting element holds the proximal end of the stylet and is fixedly attached to the distal end of the integrated spacer. The connecting elements each have an opening that facilitates insertion of the biopsy needle into a known biopsy gun in either the cocked or uncocked position. In an alternate embodiment, the guiding needle holder includes an integrated spacer that fixedly holds the stylet, and a connecting element that displaceably holds the cannula.</p>		



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LJ	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

BIOPSY NEEDLE AND SURGICAL INSTRUMENT

FIELD OF THE INVENTION

This invention relates to an improved biopsy needle specially suited for use in a biopsy gun, or for use as a surgical instrument.

BACKGROUND OF THE INVENTION

5 Biopsy needles, as part of a biopsy system, are generally used in the medical field to remove tissue, cells or fluids from a body for examination. Known biopsy needles have at least one inner needle (stylet) and an outer needle (cannula). The stylet has a point to enable insertion of the needle into a body, and a recess or notch located near its distal end for receiving a tissue sample. The cannula is displaceably guided on the stylet and has sharp
10 cutting edges. Both the stylet and cannula have a connecting element on their proximal ends to enable connection of the needle to the slides of a biopsy gun. The connecting elements in known biopsy needles generally have included either flanges that cooperate with matching contact surfaces on the slides, or recesses that engage a rib located on a slide wherein both the slide and the rib run along the length of the biopsy needle.

15 Some prior art biopsy needles have the disadvantage that it is sometimes difficult to insert them into the biopsy gun under sterile conditions. Some prior art biopsy guns require a certain spacing between the connecting elements on the stylet and cannula in order for the biopsy needle to be inserted into the biopsy gun. However, this task of inserting the biopsy needle into the biopsy gun while the connecting elements are maintained in a fixed
20 orientation is difficult because the stylet is generally freely displaceable in the cannula. Therefore, it is generally necessary to align the connecting elements of the biopsy needle, either manually or through use of a separate spacer, prior to insertion into a biopsy gun.

After the biopsy needle is inserted into a biopsy gun, if a spacer clip is used, it is generally necessary to remove the spacer in order to close the lid and operate the biopsy gun.

Conventional spacer clips require the molding of a separate spacer. This requirement of a separate molding step adds an additional step in the manufacturing and packaging process

5 thereby increasing the costs to produce the biopsy needle. Moreover, the use of a separate spacer clip may require undue handling of the needle in order to connect and disconnect the spacer clip. Furthermore, some conventional biopsy guns do not permit the option of inserting the needle into a biopsy gun in the uncocked position. By permitting a biopsy needle to be inserted in an uncocked biopsy gun, the proper operation of the needle is
10 checked prior to the gun being fired by moving the inner needle and the outer needle relative to each other during the cocking process. An additional disadvantage of some conventional biopsy needles is that under some conditions, the individual connecting elements slip or rotate relative to the slides they are carried on when inserted in a biopsy gun.

15 SUMMARY OF THE INVENTION

The present invention includes a biopsy needle particularly suited for use in a biopsy gun. Additionally, the present invention can also be used as a surgical instrument for procedures such as, a microlumpectomy and the removal of microcalcification. The biopsy needle made according to the present invention includes a guiding needle holder that is an
20 integral part of the needle itself that is not removed prior to needle use. The guiding needle holder provides not only an integrated means for grasping and handling the needle, but facilitates needle alignment without the use of extrinsic devices, and prevents rotation and other movement of the needle relative to itself and the slides in a biopsy gun. Additionally,

the integrated design of the needle allows the needle to be easily prepackaged in a sterile, disposable condition.

The biopsy needle of the present invention comprises an inner needle with a recess near its beveled distal end, an outer needle displaceably guided on the inner needle and
5 having a beveled distal end, and a guiding needle holder. The gauge and length of the inner needle and outer needle varies with the procedure for which it will be used. The guiding needle holder includes first and second connecting elements, and an integrated spacer. The first connecting element is displaceably guided along the length of the integrated spacer, and the second connecting element is fixedly engaged with the proximal end of the integrated
10 spacer. Both the first and second connecting elements contain a raised annular flange that defines a portion of a bore through the connecting element and assists in maintaining the connecting elements in engagement with the integrated spacer. These bores in the connecting elements allow the needle to be mounted on posts extending from the slides of a biopsy gun. It should be noted that these bores are illustrative of only one way to connect the needle to
15 the slides of a biopsy gun and that other arrangements may be used. The inner needle is embedded in the second connecting element and the outer needle is embedded in the first connecting element. When the first and second connecting elements are maximally displaced relative to each other within the integrated spacer, the distance between the raised annular flange in the first connecting element and the raised annular flange in the second connecting
20 element is such that the biopsy needle can be inserted with the proper spacing into a biopsy gun in the cocked position. This eliminates the need for any external means of achieving the proper spacing of the needle. Alternatively, the needle can be mounted in a biopsy gun in the uncocked position.

Additionally, the present invention can be used to take multiple samples at the same biopsy site as required by procedures such as computer tomography by removing the connecting element carrying the inner needle and replacing it with another connecting element and an inner needle. Once the body is pierced, the biopsy needle is inserted into a biopsy gun and the sample taken. The needle is then removed from the body and the biopsy gun, the sample removed, and the needle can then be reused. All this is accomplished without the use of an external spacer.

In an alternative embodiment, the guiding needle holder incorporates an integrated spacer and a single connecting element. The inner needle is embedded in the integrated spacer and the outer needle is embedded in the connecting element. The biopsy needle can be positioned for insertion into a biopsy gun either in the cocked or uncocked position by maximizing the displacement of the connecting element. In this embodiment, multiple samples can be taken by dislodging the integrated spacer, removing the inner needle and replacing it with another inner needle. The integrated spacer can either be reused or replaced.

It is therefore an advantage of the present invention to provide a biopsy needle that allows a tissue sample to be obtained from a tissue mass which automatically captures and allows the removal of a tissue sample for examination, wherein the inner needle and the outer needle reside and function in an integrated spacer.

It is a further advantage of the present invention to provide an integrated spacer or guiding needle holder that does not require the spacer to be removed prior to operating a biopsy gun.

It is a further advantage of the present invention to provide an integrated spacer that remains inside a biopsy gun during the operation of the gun.

It is a further advantage of the present invention to provide an integrated spacer for a biopsy needle which allows single-handed loading and removal of the needle from a biopsy gun while maintaining the orientation and rotational position of the inner needle and outer needle of a biopsy needle relative to each other and the biopsy gun.

5 It is a further advantage of the present invention to provide a biopsy needle available in multiple needle gauges and lengths, tailored for various biopsy procedures.

It is a further advantage of the present invention to provide a biopsy needle including an integrated spacer which allows the insertion of the needle into a body, unattached to the biopsy device, without the use of external or removable spacers, and maintains the
10 orientation and proper spacing of the first and second elements to allow the simple insertion of the biopsy needle into a biopsy gun after the needle is inserted into the body, as required by certain biopsy procedures.

It is a further advantage of the present invention to provide a biopsy needle with an integrated spacer that allows the integrated spacer to be gripped by the fingers of the user for
15 manual insertion of the needle into the body while maintaining the spacial relationship between the inner needle and the outer needle.

It is a further advantage of the present invention to provide a biopsy needle that is prepackaged, sterile and disposable.

It is a further advantage of the present invention to provide a biopsy needle which can
20 be used to obtain multiple biopsy samples from the same biopsy site without the use of an external spacer.

Other features and advantages of the present invention will become readily apparent from the following detailed description, the appended claims and the accompanying drawings. It is to be understood that both the foregoing general description and the following

detailed description are exemplary and provided for purposes of explanation only, and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTIONS OF DRAWINGS:

5 Fig. 1a is an isometric view of one embodiment of the biopsy needle made according to the present invention;

 Fig. 1b is an exploded view of the biopsy needle made according to the present invention, positioned so that the recess in the inner needle is exposed;

 Fig. 2a is an end view of the integrated spacer;

10 Fig. 2b is an end view of a connecting element;

 Fig. 3a is an end view demonstrating how the connecting elements are inserted into the integrated spacer to form the guiding needle holder;

 Fig. 3b is an end view of the assembled guiding needle holder;

 Fig. 4a is an isometric view of an alternative embodiment of the biopsy needle;

15 Fig. 4b is the bottom view of an alternative embodiment of the biopsy needle; and

 Fig. 5 is an isometric view of one embodiment of the biopsy needle of the present invention used in conjunction with a biopsy gun of a type that is well-known in the art.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

20

 Figs. 1a and 1b show a preferred embodiment of the biopsy needle 10 made according to the present invention which comprises a guiding needle holder 8, an inner needle 12 and an outer needle 14. The design of the inner needle 12 and the outer needle 14 is generally well known in the art and both have a beveled cutting edge on their distal ends. The inner

needle 12 and the outer needle 14 may be of a variety of gauge sizes. The guiding needle holder 8, is used to maintain the relative orientation of the inner needle 12 and the outer needle 14, and to provide a means by which the biopsy needle 10 can be grasped. The guiding needle holder 8 includes an integrated spacer 20, and first and second connecting elements, 16 and 18 respectively.

The integrated spacer 20 has an elongated body which includes a slot 28 that extends longitudinally a predetermined distance and a hole 26 that facilitate the insertion of the biopsy needle 10 into a biopsy gun of a type known in the art. As illustrated in Fig. 2a, the integrated spacer 20 has an interior portion 21 that includes a longitudinally extended angled wall 30, a longitudinally extending curved wall 39, and a groove 31, that facilitate the assembly and operation of the biopsy needle 10. The groove 31, angled wall 30, and the curved wall 39, extend longitudinally from the distal end 17 of the integrated spacer 20 through the entire length of the spacer 20. Alternatively, an end wall at the proximal end of the spacer 20 may be provided. The interior portion 21 is configured such that its cross-sectional profile is similar to the cross-sectional profile of the first and second connecting elements 16 and 18 of the needle 10 shown in Fig. 1b.

The first connecting element 16, shown in Fig. 2b, includes a protruding section 33, a sidewall section including a curved portion 35 and a flat portion 36, a longitudinally extending bore 32A that goes through the entire length of the first connecting element 16, and a vertically extending bore 23 which is partially defined by a raised annular flange 22. A portion of the bore 32A is defined by a cylindrical sleeve 34 positioned on one end of the first connecting element 16 shown in Fig. 1b.

For purposes of clarification, when referring to the longitudinally extending bore through second connecting element 18, the longitudinally extending bore will be referred to

with reference numeral 32B. The second connecting element 18, illustrated in Fig. 1b, is identical to the first connecting element 16, except that the longitudinally extending bore 32B is not required to extend through the entire length of the second connecting element 18.

However, for purposes of ease of manufacture, connecting elements 16 and 18 may be identical. The longitudinally extending bore 32A of the first connecting element 16 holds the proximal end of the outer needle 14 and the longitudinally extending bore 32B of the second connecting element 18 holds the proximal end of the inner needle 12. The connecting elements 16 and 18 are preferably formed by insert molding techniques generally known in the art. The connecting elements 16 and 18 are insert molded around outer needle 14 and inner needle 12, respectively. Although the preferred embodiment illustrates a vertically extending bore 23 in the connecting elements 16 and 18 for engagement to the slides of a biopsy gun, other configurations may be used, such as, for example, flanges.

To assemble the biopsy needle 10, the proximal end portion of the outer needle 14 is fixedly carried in the longitudinally extending bore 32A of the first connecting element 16. The proximal end of the inner needle 12 is removable and fixedly inserted into the longitudinally extending bore 32B of the second connecting element 18. The inner needle 12 is then inserted into the outer needle 14 until the first and second connecting elements 16 and 18 meet. In order to insert the first and second connecting elements 16 and 18 in the integrated spacer 20, both connecting elements 16 and 18 are initially engaged into the integrated spacer 20 with curved portion 35 engaged with the curved wall 39 and flat portion 36 engaged with angled wall 30, as illustrated in Fig. 3a. The second connecting element 18 is rotated into the integrated spacer 20 until the protruding portion 33 snaps into the groove 31 and the second raised annular flange 24 fits into the hole 26 in the integrated spacer 20. The first connecting element 16 is rotated into the integrated spacer 20 until the protruding

section 33 snaps into the groove 31 and the first raised annular flange 22 in the first connecting element 16 fits into the slot 28 in the integrated spacer 20, as shown in Fig. 3b. In general use, the biopsy needle 10 remains in this attached configuration throughout its insertion into a biopsy gun and its subsequent use. The length of the longitudinal slot 28 is such that when the outer needle 14 is fully extended, the distance between the first raised annular flange 22 in the first connecting element 16 and the second raised annular flange 24 in the second connecting element 18 is sufficient to enable the flanges to align with the posts on the slides of a biopsy gun when the slides are in the cocked or uncocked positions. The dimensions of the guiding needle holder 8 and the longitudinal slot 28 may be configured to allow the biopsy needle 10 of the present invention to be used in various biopsy guns.

The biopsy needle 10 made according to the present invention provides several advantages over conventional biopsy needles and even those conventional biopsy needles that employ separate spacer clips. For example, when the biopsy needle 10 of the present invention is in its assembled form as illustrated in Fig. 1a, the first connecting element 16 is in the maximally displaced position within the integrated spacer 20. The body of the integrated spacer 20 permits the user to easily grasp the biopsy needle 10 without moving the position of connecting elements 16 and 18 relative to each other. In this position, the distance between the first raised annular flange 22 in the first connecting element 16 and the second raised annular flange 24 in the second connecting element 18 is sufficient to align these holes with posts located on the slides of a cocked biopsy gun, and therefore enable the biopsy needle 10 to be loaded into a biopsy gun without manipulation of the connecting elements 16 and 18. The tip of the inner needle 12 is exposed to facilitate insertion of the biopsy needle 10 into the tissue being sampled.

The biopsy needle 10 including the integrated spacer 20 can be inserted into a biopsy gun either in the cocked or uncocked position to accommodate the user's preference. The integrated spacer 20 also facilitates removal of the biopsy needle 10 from a biopsy gun without the necessity to reattach a spacer clip as is required with conventional biopsy needles. If the biopsy needle 10 is inserted while the gun is uncocked, the gun should be cocked prior to use. Insertion of the biopsy needle 10 into a biopsy gun 60 is generally straight forward as shown in Fig. 5. The body of the needle holder 8 is grasped by the user and placed over the interior chamber of the biopsy gun 60, as illustrated in Fig. 5. Vertically extending bore 23 of the first and second connecting elements 16 and 18 are aligned over slides 62 of the biopsy gun 60 and receive posts 64. Without having to remove the integrated spacer 20, the lid to the biopsy gun 60 is closed and is ready for use.

The tip of the biopsy needle 10 is inserted into the tissue to be sampled. The biopsy gun is then triggered and the second connecting element 18 along with the integrated spacer 20 is moved forward, while the first connecting element 16 is held stationary. This action is accomplished through the novel arrangement of the guiding needle holder 8 wherein flange 24 of second connecting element 18 engages hole 26 while flange 22 of the first connecting element 16 moves relative to the integrated spacer 20 in slot 28. This movement causes the inner needle 12 to move forward into the tissue being sampled and exposes the recess 13 in the inner needle 12 which receives the tissue to be sampled. The second slide of the biopsy gun is triggered moving the slide engaged with the first connecting element 16 forward. This action causes the outer needle 14 to move forward over the recess 13 which causes the outer needle 14 to separate tissue prolapsed in the recess 13 and secure it therein. The biopsy needle 10, at this point, is back in the position illustrated in Fig. 1a. The biopsy needle 10 can then be removed and the tissue examined. The integrated spacer 20 in engagement with

the first and second connecting elements 16 and 18 during operation of the biopsy gun 60, stabilizes the first and second connecting elements 16 and 18 and prevents twisting and bending in the biopsy gun 60.

Multiple samples can be taken at the same biopsy site by either reusing the biopsy
5 needle 10 or replacing the inner needle 12. The inner needle 12 is replaced by removing the second connecting element 18 from the integrated spacer 20, sliding the inner needle 12 out of the outer needle 14, and inserting another inner needle into the outer needle 14 and reattaching the second connecting element 18 in the manner previously described. The second connecting element 18 can either be reused or replaced.

10 An alternative embodiment of the invention is shown in Figs. 4a and 4b. In this embodiment the biopsy needle 10A includes an inner needle 42, an outer needle 44, and a guiding needle holder 40. The guiding needle holder 40 comprises an integrated spacer 48 and a connecting element 50. Connecting element 50 is identical to connecting element 16 previously described. The integrated spacer is substantially identical to integrated holder 20,
15 except that longitudinally extending groove 31, longitudinally extending wall 30 and longitudinally extending curved wall 39 do not extend as far in the body of the spacer 20. The proximal end of the spacer 48 is solid for ease of manufacturing and includes a vertically extending bore 41. An inner needle 42 is fixedly attached to the integrated spacer 48 near the proximal end, and the outer needle 44 is fixedly attached to the connecting element 50. The
20 connecting element 50 can be attached to the integrated spacer 48 in the manner previously described herewith for attaching the first connecting element 16 in the previous embodiment.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is

intended that the specification and examples be considered as exemplary only, with the true scope and spirit of the invention being indicated by the following claims.

We claim:

1. A biopsy needle comprising:
 - 2 a guiding needle holder;
an inner needle having a recess in a vicinity of a distal end thereof for receiving a
4 tissue sample, and a proximal end fixedly connected to said guiding needle holder such that
said inner needle does not move relative to said guiding needle holder; and
6 an outer needle substantially coaxial with said inner needle and disposed about a
portion of said inner needle having a proximal end displaceably connected to said guiding
8 needle holder such that said outer needle moves longitudinally relative to said guiding needle
holder.
2. A biopsy needle as claimed in claim 1, wherein said guiding needle holder comprises:
 - 2 an integrated spacer;
a first connecting element displaceably attached to said integrated spacer and movable
4 therein; wherein said outer needle is connected to the first connecting element; and
a second connecting element fixedly connected to said integrated spacer such that said
6 second connecting element does not move relative to said integrated spacer, wherein said
inner needle is fixedly attached to the second connecting element.
3. A biopsy needle as claimed in claim 2, wherein said integrated spacer includes
 - 2 a hole and a slot;
said first connecting element includes a first annular flange displaceably engaged to
4 the slot of the integrated spacer; and

6 said second connecting element includes a second annular flange fixedly engaged to the hole of said integrated spacer.

4. A biopsy needle as claimed in claim 3, wherein said first connecting element is
2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient to enable operation of said biopsy needle in a biopsy gun.

5. A biopsy needle as claimed in claim 4, wherein said first connecting element is
2 positioned along the length of the slot of said integrated spacer a predetermined distance to enable insertion of said biopsy needle in a biopsy gun.

6. A biopsy needle as claimed in claim 5, wherein
2 said integrated spacer having an interior section including a longitudinally extending groove, a curved wall, and an angled wall;
4 said first connecting element includes a first protruding section engaged to the groove of said integrated spacer, a first curved portion that fits in the curved wall of said integrated
6 spacer; and
 said second connecting element includes a second protruding section engaged to the
8 groove of said integrated spacer, and a second curved portion engaged to the curved wall of said integrated spacer.

7. A biopsy needle as claimed in claim 1, wherein said guiding needle holder comprises:
2 an integrated spacer wherein said inner needle is fixedly connected to the integrated spacer such that said inner needle does not move relative to said integrated spacer; and

- 4 a connecting element displaceably connected to said integrated spacer movable
therein wherein said outer needle is fixedly connected to the connecting element.
8. A biopsy needle as claimed in claim 7, wherein
2 said integrated spacer includes a first hole and a slot;
 said connecting element includes an annular flange displaceably connected in the slot
4 of said integrated spacer.
9. A biopsy needle as claimed in claim 8, wherein the connecting element is
2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient
to enable insertion of said biopsy needle into a biopsy gun.
10. A biopsy needle as claimed in claim 9, wherein
2 said integrated spacer includes a longitudinally extending groove, a curved wall, and
an angled wall; and
4 said connecting element includes a protruding section engaged to the groove of said
integrated spacer, a curved portion that fits in the curved wall of said integrated spacer, and a
6 flat portion.
11. A needle holder for guiding a biopsy needle, comprising:
2 an integrated spacer;
 a first connecting element fixedly connected to said integrated spacer; and

4 a second connecting element displaceably connected to said integrated spacer such
that said second connecting element is longitudinally displaceably along said integrated
6 spacer.

12. A guiding needle holder as claimed in claim 11, wherein
2 said integrated spacer includes a hole and a slot;
 said first connecting element includes a first annular flange connected in the slot of
4 the integrated spacer such that it is displaceable relative to said integrated spacer; and
 said second connecting element includes a second annular flange fixedly connected to
6 the first hole in said integrated spacer.-

13. A guiding needle holder as claimed in claim 12, wherein the second connecting
2 element is displaceably guided along the length of the slot of said integrated spacer a distance
sufficient to enable insertion of a biopsy needle into a biopsy gun.

14. A guiding needle holder as claimed in claim 13, wherein
2 said integrated spacer includes a longitudinally extending groove, a curved wall, and
an angled wall;
4 said first connecting element includes a first protruding section that fits in the groove
of said integrated spacer, a first curved portion that fits in the curved wall of said integrated
6 spacer, a first flat portion, and a first longitudinal bore; and
 said second connecting element includes a second protruding section that fits in the
8 groove of said integrated spacer, a second curved portion that fits in the curved wall of said
integrated spacer, a second flat portion and a second longitudinal bore.

15. A needle holder for guiding a biopsy needle comprising:
2 an integrated spacer; and
a connecting element displaceably attached to said integrated spacer.
16. A guiding needle holder as claimed in claim 15, wherein the integrated spacer
2 includes
a first hole and a slot; and
4 said connecting element includes a raised hole displaceably connected in the slot in
said integrated spacer.
17. A guiding needle holder as claimed in claim 16, wherein said connecting element is
2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient
to enable insertion of a biopsy needle into a biopsy gun.
18. A guiding needle holder as claimed in claim 17, wherein,
2 said integrated spacer includes a longitudinally extending groove, a curved wall, an
angled wall, and a first longitudinal bore; and
4 said connecting element includes a protruding section that fits in the groove of said
integrated spacer, a curved portion that fits in the curved wall of said integrated spacer, a flat
6 portion, and a second longitudinal bore.
19. A biopsy instrument for use in a biopsy gun comprising:
2 a hollow outer needle;

an inner needle extending through said hollow outer needle, wherein said inner needle
4 includes a recess near the distal end thereof, said inner needle and said outer needle movable
relative to each other permitting selective encapsulation of said recess on said inner needle by
6 said outer needle;

a first connecting element attached to a proximal end of said outer needle
8 a second connecting element attached to a proximal end of said inner needle and
positioned in the same plane as said first connecting element; and

10 an integrated spacer having an interior section, said first and second connecting
elements engaged to said interior section, and moveable therein relative to each other
12 between a spaced apart orientation and an adjacent orientation whereby said inner needle is
selectively moved between positions exposing the recess of said inner needle and
14 encapsulating the recess of said inner needle when said integrated spacer is positioned within
a biopsy gun.

21. A biopsy instrument for use in a biopsy gun comprising:

2 a hollow outer needle;

an inner needle extending through said hollow outer needle, wherein said inner needle
4 includes a recess near the distal end thereof, said inner needle and said outer needle movable
relative to each other permitting selective encapsulation of said recess on said inner needle by
6 said outer needle;

a connecting element attached to a proximal end of said outer needle; and

8 an integrated spacer attached to a proximal end of said inner needle, said connecting
element engaged to said integrated spacer for relative movement therein whereby said inner
10 needle is selectively moved between positions exposing the recess of said inner needle and

- encapsulating the recess of said inner needle when said biopsy instrument is contained within
- 12 a biopsy gun.

FIG. 1a

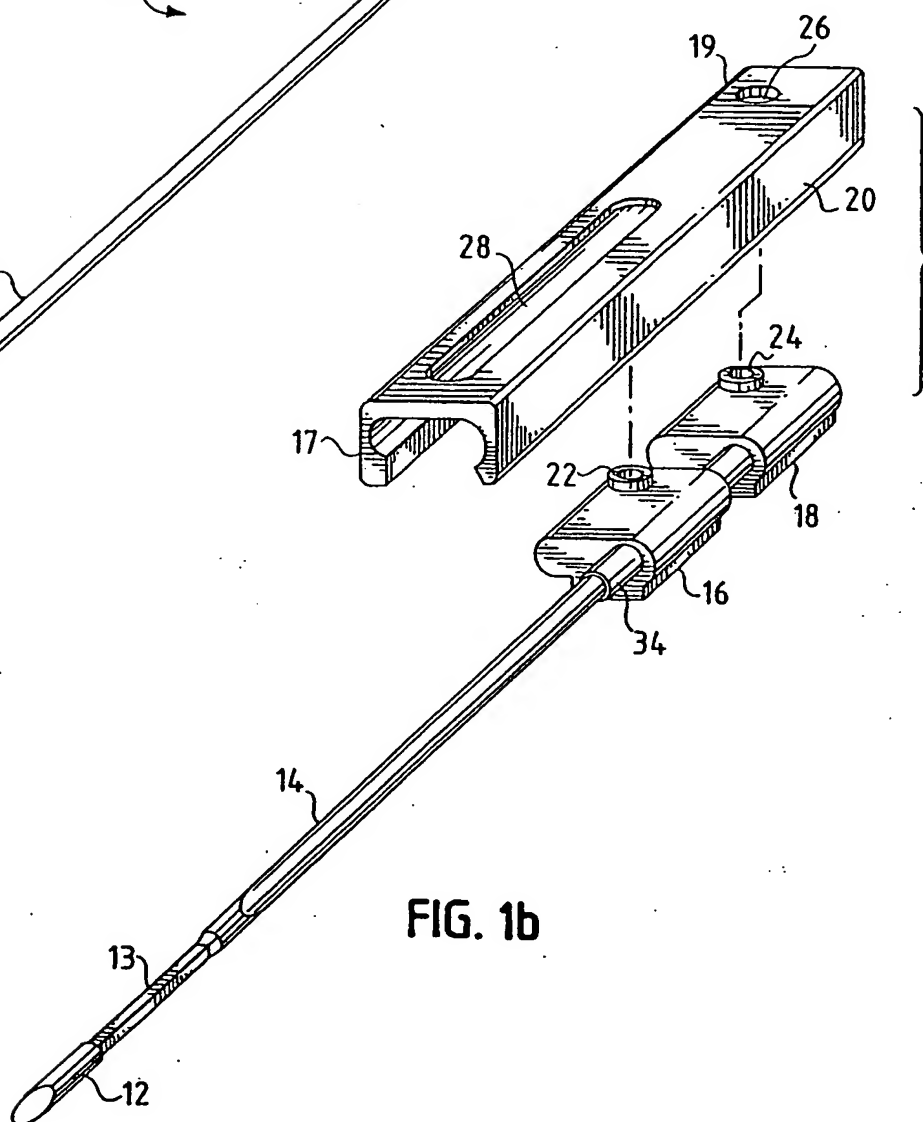
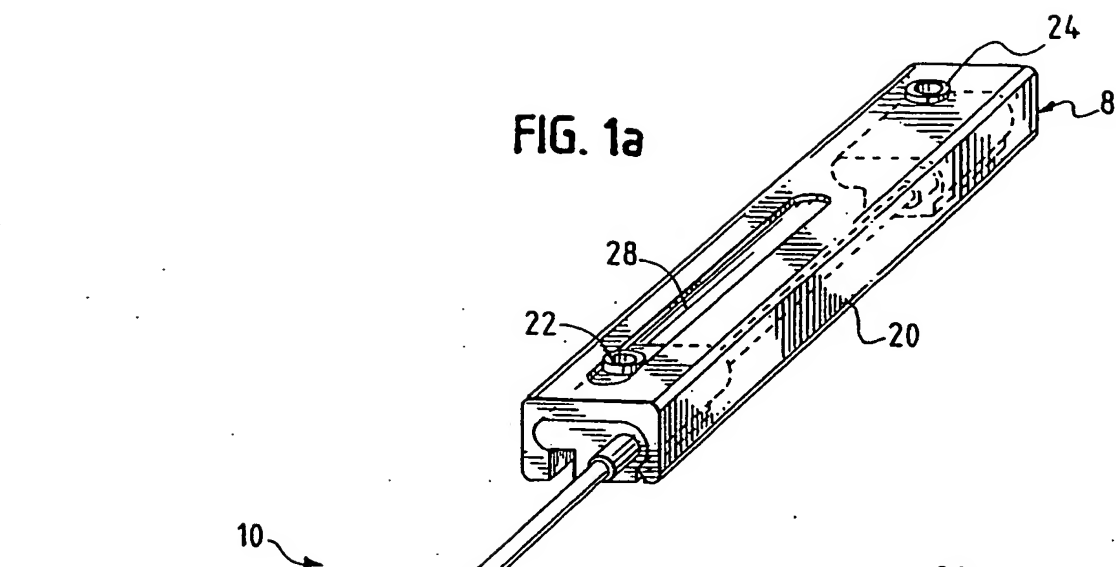


FIG. 1b

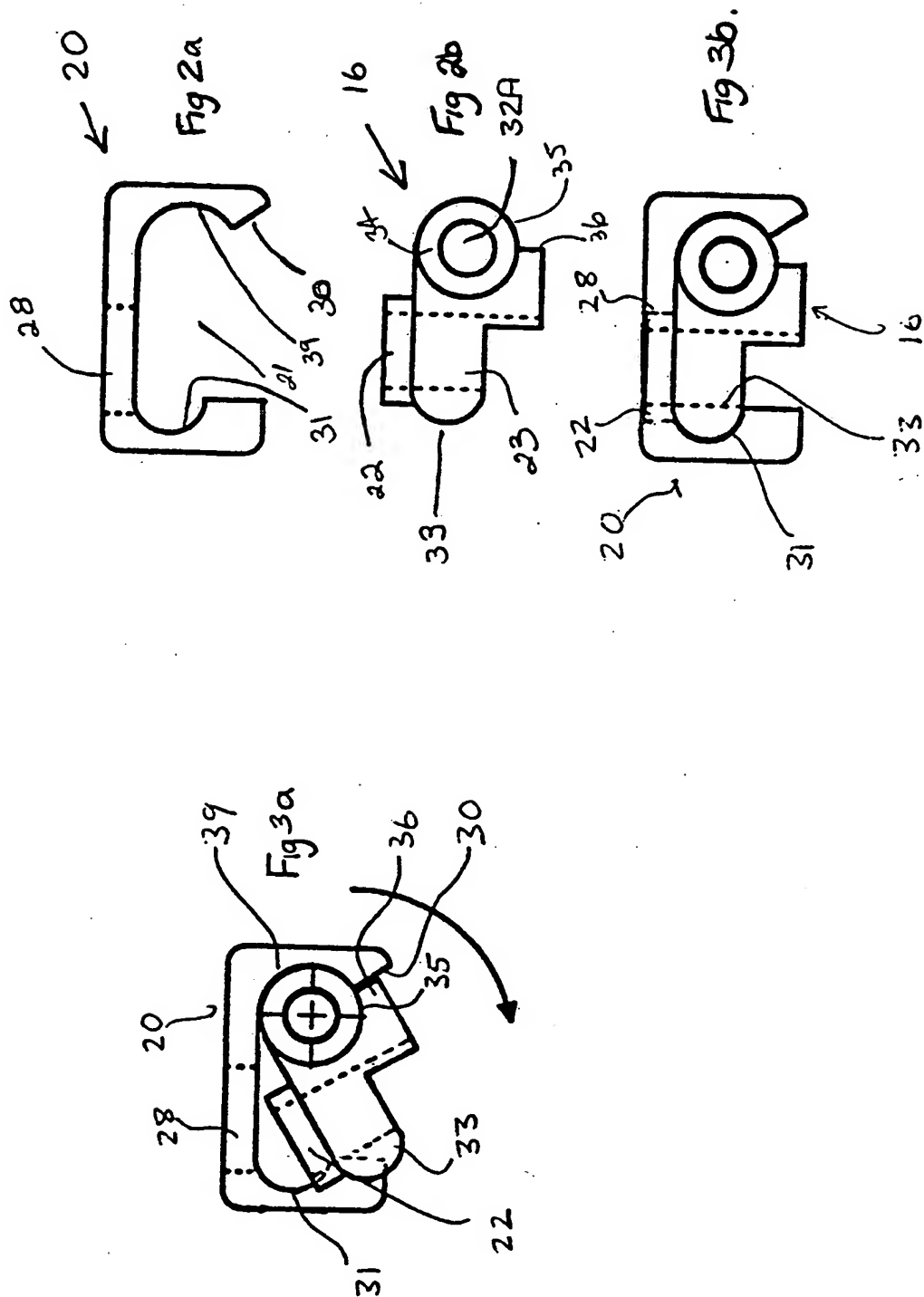


FIG. 4a

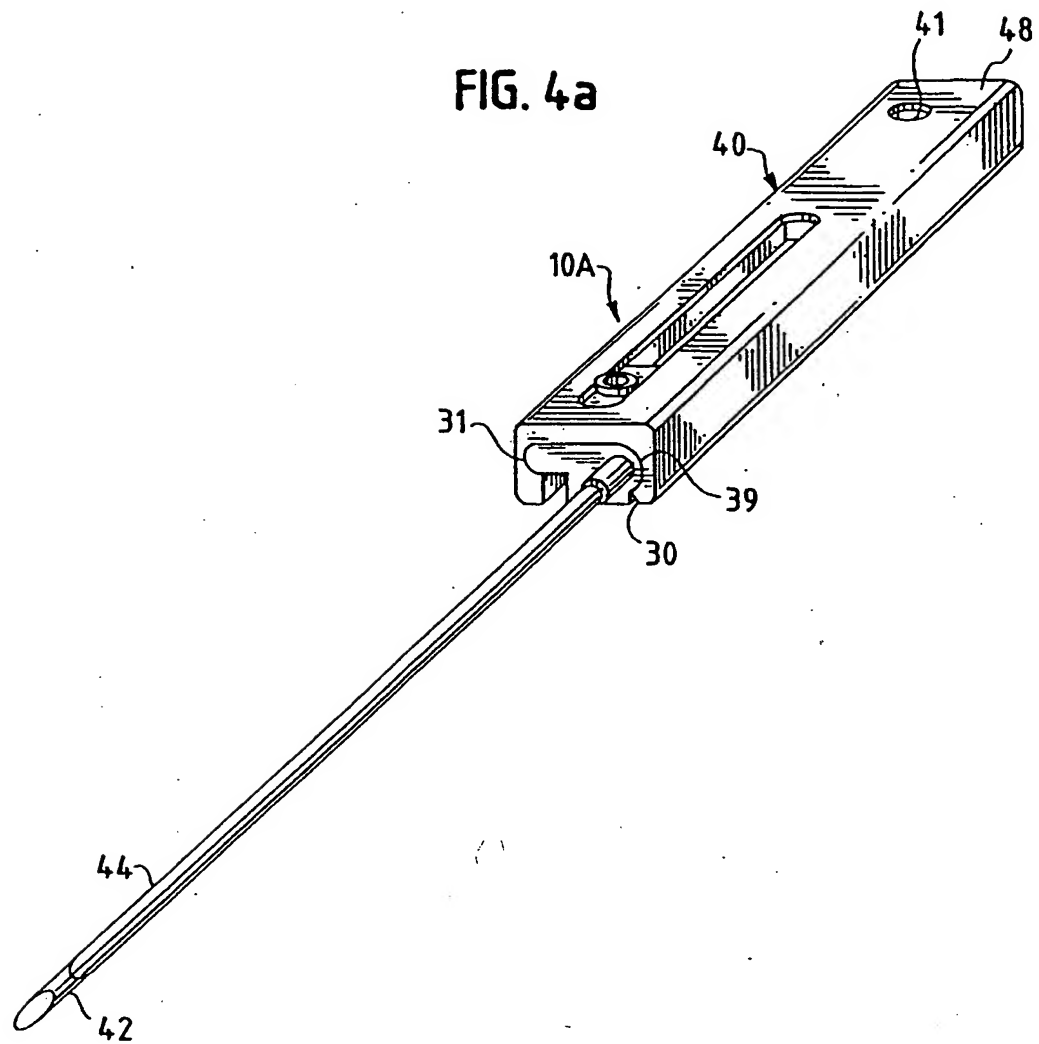


FIG. 4b

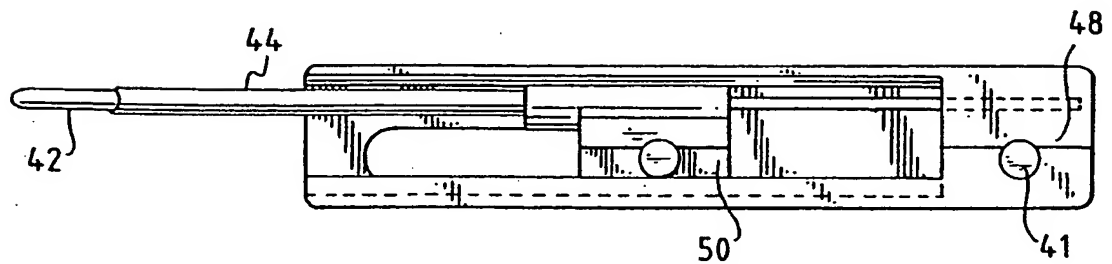
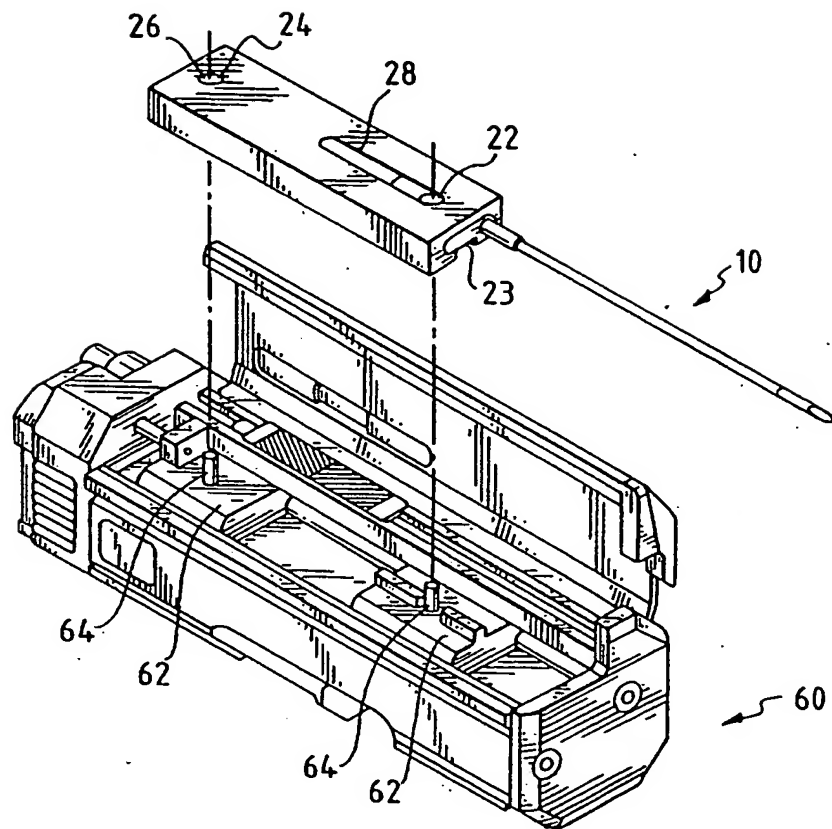


FIG. 5



CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



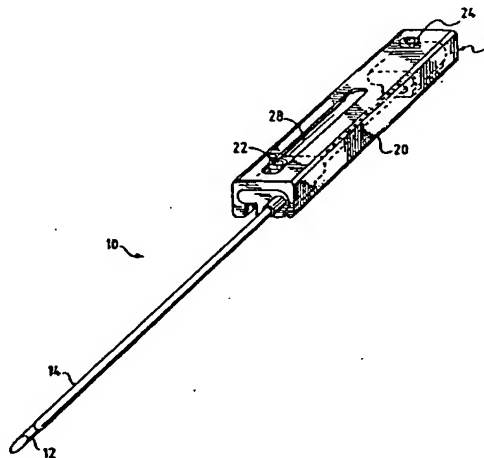
(43) International Publication Date
12 October 2000 (12.10.2000)

PCT

(10) International Publication Number
WO 00/59378 A3

- (51) International Patent Classification⁷: A61B 10/00 (81) Designated State (*national*): JP.
- (21) International Application Number: PCT/IB99/02131 (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (22) International Filing Date: 13 July 1999 (13.07.1999)
- (25) Filing Language: English Published:
— with international search report
- (26) Publication Language: English
- (88) Date of publication of the international search report:
12 July 2001
- (30) Priority Data:
09/114,509 13 July 1998 (13.07.1998) US
- (48) Date of publication of this corrected version:
22 November 2001
- (71) Applicant: MEDICAL DEVICE TECHNOLOGIES, INC. [US/US]; 4445-310 S.W. 35th Terrace, Gainesville, FL 32608 (US).
- (15) Information about Correction:
see PCT Gazette No. 47/2001 of 22 November 2001, Section II
- (72) Inventor: TERWILLIGER, Richard; 332 Ute Lane South, Estes Park, CO 80517 (US).
- (74) Agents: TANG, Wayne, L. et al.; Mayer Brown & Platt, P.O. Box 2828, Chicago, IL 60690-2828 (US).
- (54) Title: BIOPSY NEEDLE AND SURGICAL INSTRUMENT

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 00/59378 A3

(57) Abstract: The present invention includes a biopsy needle for use in a biopsy gun or as surgical instrument, capable of taking multiple samples, and a guiding needle holder for holding a biopsy needle. The biopsy needle includes an inner needle, also called a stylet, and an outer needle, also called a cannula, and a guiding needle holder. The stylet has a recess in the vicinity of its distal end which receives the tissue sample. The guiding needle holder includes an integrated spacer, and first and second connecting elements. The first connecting element holds the proximal end of the cannula and is displaceably attached along the length of the integrated spacer. The second connecting element holds the proximal end of the stylet and is fixedly attached to the distal end of the integrated spacer. The connecting elements each have an opening that facilitates insertion of the biopsy needle into a known biopsy gun in either the cocked or uncocked position. In an alternate embodiment, the guiding needle holder includes an integrated spacer that fixedly holds the stylet, and a connecting element that displaceably holds the cannula.

BIOPSY NEEDLE AND SURGICAL INSTRUMENT

FIELD OF THE INVENTION

This invention relates to an improved biopsy needle specially suited for use in a biopsy gun, or for use as a surgical instrument.

BACKGROUND OF THE INVENTION

5 Biopsy needles, as part of a biopsy system, are generally used in the medical field to remove tissue, cells or fluids from a body for examination. Known biopsy needles have at least one inner needle (stylet) and an outer needle (cannula). The stylet has a point to enable insertion of the needle into a body, and a recess or notch located near its distal end for receiving a tissue sample. The cannula is displaceably guided on the stylet and has sharp
10 cutting edges. Both the stylet and cannula have a connecting element on their proximal ends to enable connection of the needle to the slides of a biopsy gun. The connecting elements in known biopsy needles generally have included either flanges that cooperate with matching contact surfaces on the slides, or recesses that engage a rib located on a slide wherein both the slide and the rib run along the length of the biopsy needle.

15 Some prior art biopsy needles have the disadvantage that it is sometimes difficult to insert them into the biopsy gun under sterile conditions. Some prior art biopsy guns require a certain spacing between the connecting elements on the stylet and cannula in order for the biopsy needle to be inserted into the biopsy gun. However, this task of inserting the biopsy needle into the biopsy gun while the connecting elements are maintained in a fixed
20 orientation is difficult because the stylet is generally freely displaceable in the cannula. Therefore, it is generally necessary to align the connecting elements of the biopsy needle, either manually or through use of a separate spacer, prior to insertion into a biopsy gun.

After the biopsy needle is inserted into a biopsy gun, if a spacer clip is used, it is generally necessary to remove the spacer in order to close the lid and operate the biopsy gun.

Conventional spacer clips require the molding of a separate spacer. This requirement of a separate molding step adds an additional step in the manufacturing and packaging process

5 thereby increasing the costs to produce the biopsy needle. Moreover, the use of a separate spacer clip may require undue handling of the needle in order to connect and disconnect the spacer clip. Furthermore, some conventional biopsy guns do not permit the option of

inserting the needle into a biopsy gun in the uncocked position. By permitting a biopsy needle to be inserted in an uncocked biopsy gun, the proper operation of the needle is

10 checked prior to the gun being fired by moving the inner needle and the outer needle relative to each other during the cocking process. An additional disadvantage of some conventional biopsy needles is that under some conditions, the individual connecting elements slip or rotate relative to the slides they are carried on when inserted in a biopsy gun.

15 SUMMARY OF THE INVENTION

The present invention includes a biopsy needle particularly suited for use in a biopsy gun. Additionally, the present invention can also be used as a surgical instrument for procedures such as, a microlumpectomy and the removal of microcalcification. The biopsy needle made according to the present invention includes a guiding needle holder that is an

20 integral part of the needle itself that is not removed prior to needle use. The guiding needle holder provides not only an integrated means for grasping and handling the needle, but facilitates needle alignment without the use of extrinsic devices, and prevents rotation and other movement of the needle relative to itself and the slides in a biopsy gun. Additionally,

the integrated design of the needle allows the needle to be easily prepackaged in a sterile, disposable condition.

The biopsy needle of the present invention comprises an inner needle with a recess near its beveled distal end, an outer needle displaceably guided on the inner needle and having a beveled distal end, and a guiding needle holder. The gauge and length of the inner
5 needle and outer needle varies with the procedure for which it will be used. The guiding needle holder includes first and second connecting elements, and an integrated spacer. The first connecting element is displaceably guided along the length of the integrated spacer, and the second connecting element is fixedly engaged with the proximal end of the integrated
10 spacer. Both the first and second connecting elements contain a raised annular flange that defines a portion of a bore through the connecting element and assists in maintaining the connecting elements in engagement with the integrated spacer. These bores in the connecting elements allow the needle to be mounted on posts extending from the slides of a biopsy gun. It should be noted that these bores are illustrative of only one way to connect the needle to
15 the slides of a biopsy gun and that other arrangements may be used. The inner needle is embedded in the second connecting element and the outer needle is embedded in the first connecting element. When the first and second connecting elements are maximally displaced relative to each other within the integrated spacer, the distance between the raised annular flange in the first connecting element and the raised annular flange in the second connecting
20 element is such that the biopsy needle can be inserted with the proper spacing into a biopsy gun in the cocked position. This eliminates the need for any external means of achieving the proper spacing of the needle. Alternatively, the needle can be mounted in a biopsy gun in the uncocked position.

Additionally, the present invention can be used to take multiple samples at the same biopsy site as required by procedures such as computer tomography by removing the connecting element carrying the inner needle and replacing it with another connecting element and an inner needle. Once the body is pierced, the biopsy needle is inserted into a biopsy gun and the sample taken. The needle is then removed from the body and the biopsy gun, the sample removed, and the needle can then be reused. All this is accomplished without the use of an external spacer.

In an alternative embodiment, the guiding needle holder incorporates an integrated spacer and a single connecting element. The inner needle is embedded in the integrated spacer and the outer needle is embedded in the connecting element. The biopsy needle can be positioned for insertion into a biopsy gun either in the cocked or uncocked position by maximizing the displacement of the connecting element. In this embodiment, multiple samples can be taken by dislodging the integrated spacer, removing the inner needle and replacing it with another inner needle. The integrated spacer can either be reused or replaced.

It is therefore an advantage of the present invention to provide a biopsy needle that allows a tissue sample to be obtained from a tissue mass which automatically captures and allows the removal of a tissue sample for examination, wherein the inner needle and the outer needle reside and function in an integrated spacer.

It is a further advantage of the present invention to provide an integrated spacer or guiding needle holder that does not require the spacer to be removed prior to operating a biopsy gun.

It is a further advantage of the present invention to provide an integrated spacer that remains inside a biopsy gun during the operation of the gun.

It is a further advantage of the present invention to provide an integrated spacer for a biopsy needle which allows single-handed loading and removal of the needle from a biopsy gun while maintaining the orientation and rotational position of the inner needle and outer needle of a biopsy needle relative to each other and the biopsy gun.

5 It is a further advantage of the present invention to provide a biopsy needle available in multiple needle gauges and lengths, tailored for various biopsy procedures.

 It is a further advantage of the present invention to provide a biopsy needle including an integrated spacer which allows the insertion of the needle into a body, unattached to the biopsy device, without the use of external or removable spacers, and maintains the
10 orientation and proper spacing of the first and second elements to allow the simple insertion of the biopsy needle into a biopsy gun after the needle is inserted into the body, as required by certain biopsy procedures.

 It is a further advantage of the present invention to provide a biopsy needle with an integrated spacer that allows the integrated spacer to be gripped by the fingers of the user for
15 manual insertion of the needle into the body while maintaining the spacial relationship between the inner needle and the outer needle.

 It is a further advantage of the present invention to provide a biopsy needle that is prepackaged, sterile and disposable.

 It is a further advantage of the present invention to provide a biopsy needle which can
20 be used to obtain multiple biopsy samples from the same biopsy site without the use of an external spacer.

 Other features and advantages of the present invention will become readily apparent from the following detailed description, the appended claims and the accompanying drawings. It is to be understood that both the foregoing general description and the following

detailed description are exemplary and provided for purposes of explanation only, and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTIONS OF DRAWINGS:

5 Fig. 1a is an isometric view of one embodiment of the biopsy needle made according to the present invention;

 Fig. 1b is an exploded view of the biopsy needle made according to the present invention, positioned so that the recess in the inner needle is exposed;

 Fig. 2a is an end view of the integrated spacer;

10 Fig. 2b is an end view of a connecting element;

 Fig. 3a is an end view demonstrating how the connecting elements are inserted into the integrated spacer to form the guiding needle holder;

 Fig. 3b is an end view of the assembled guiding needle holder;

 Fig. 4a is an isometric view of an alternative embodiment of the biopsy needle;

15 Fig. 4b is the bottom view of an alternative embodiment of the biopsy needle; and

 Fig. 5 is an isometric view of one embodiment of the biopsy needle of the present invention used in conjunction with a biopsy gun of a type that is well-known in the art.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

20

 Figs. 1a and 1b show a preferred embodiment of the biopsy needle 10 made according to the present invention which comprises a guiding needle holder 8, an inner needle 12 and an outer needle 14. The design of the inner needle 12 and the outer needle 14 is generally well known in the art and both have a beveled cutting edge on their distal ends. The inner

needle 12 and the outer needle 14 may be of a variety of gauge sizes. The guiding needle holder 8, is used to maintain the relative orientation of the inner needle 12 and the outer needle 14, and to provide a means by which the biopsy needle 10 can be grasped. The guiding needle holder 8 includes an integrated spacer 20, and first and second connecting elements, 16 and 18 respectively.

The integrated spacer 20 has an elongated body which includes a slot 28 that extends longitudinally a predetermined distance and a hole 26 that facilitate the insertion of the biopsy needle 10 into a biopsy gun of a type known in the art. As illustrated in Fig. 2a, the integrated spacer 20 has an interior portion 21 that includes a longitudinally extended angled wall 30, a longitudinally extending curved wall 39, and a groove 31, that facilitate the assembly and operation of the biopsy needle 10. The groove 31, angled wall 30, and the curved wall 39, extend longitudinally from the distal end 17 of the integrated spacer 20 through the entire length of the spacer 20. Alternatively, an end wall at the proximal end of the spacer 20 may be provided. The interior portion 21 is configured such that its cross-sectional profile is similar to the cross-sectional profile of the first and second connecting elements 16 and 18 of the needle 10 shown in Fig. 1b.

The first connecting element 16, shown in Fig. 2b, includes a protruding section 33, a sidewall section including a curved portion 35 and a flat portion 36, a longitudinally extending bore 32A that goes through the entire length of the first connecting element 16, and a vertically extending bore 23 which is partially defined by a raised annular flange 22. A portion of the bore 32A is defined by a cylindrical sleeve 34 positioned on one end of the first connecting element 16 shown in Fig. 1b.

For purposes of clarification, when referring to the longitudinally extending bore through second connecting element 18, the longitudinally extending bore will be referred to

with reference numeral 32B. The second connecting element 18, illustrated in Fig. 1b, is identical to the first connecting element 16, except that the longitudinally extending bore 32B is not required to extend through the entire length of the second connecting element 18.

However, for purposes of ease of manufacture, connecting elements 16 and 18 may be

5 identical. The longitudinally extending bore 32A of the first connecting element 16 holds the proximal end of the outer needle 14 and the longitudinally extending bore 32B of the second connecting element 18 holds the proximal end of the inner needle 12. The connecting elements 16 and 18 are preferably formed by insert molding techniques generally known in the art. The connecting elements 16 and 18 are insert molded around outer needle 14 and
10 inner needle 12, respectively. Although the preferred embodiment illustrates a vertically extending bore 23 in the connecting elements 16 and 18 for engagement to the slides of a biopsy gun, other configurations may be used, such as, for example, flanges.

To assemble the biopsy needle 10, the proximal end portion of the outer needle 14 is fixedly carried in the longitudinally extending bore 32A of the first connecting element 16.

15 The proximal end of the inner needle 12 is removable and fixedly inserted into the longitudinally extending bore 32B of the second connecting element 18. The inner needle 12 is then inserted into the outer needle 14 until the first and second connecting elements 16 and 18 meet. In order to insert the first and second connecting elements 16 and 18 in the integrated spacer 20, both connecting elements 16 and 18 are initially engaged into the
20 integrated spacer 20 with curved portion 35 engaged with the curved wall 39 and flat portion 36 engaged with angled wall 30, as illustrated in Fig. 3a. The second connecting element 18 is rotated into the integrated spacer 20 until the protruding portion 33 snaps into the groove 31 and the second raised annular flange 24 fits into the hole 26 in the integrated spacer 20. The first connecting element 16 is rotated into the integrated spacer 20 until the protruding

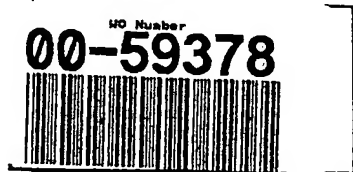
section 33 snaps into the groove 31 and the first raised annular flange 22 in the first connecting element 16 fits into the slot 28 in the integrated spacer 20, as shown in Fig. 3b. In general use, the biopsy needle 10 remains in this attached configuration throughout its insertion into a biopsy gun and its subsequent use. The length of the longitudinal slot 28 is such that when the outer needle 14 is fully extended, the distance between the first raised annular flange 22 in the first connecting element 16 and the second raised annular flange 24 in the second connecting element 18 is sufficient to enable the flanges to align with the posts on the slides of a biopsy gun when the slides are in the cocked or uncocked positions. The dimensions of the guiding needle holder 8 and the longitudinal slot 28 may be configured to allow the biopsy needle 10 of the present invention to be used in various biopsy guns.

The biopsy needle 10 made according to the present invention provides several advantages over conventional biopsy needles and even those conventional biopsy needles that employ separate spacer clips. For example, when the biopsy needle 10 of the present invention is in its assembled form as illustrated in Fig. 1a, the first connecting element 16 is in the maximally displaced position within the integrated spacer 20. The body of the integrated spacer 20 permits the user to easily grasp the biopsy needle 10 without moving the position of connecting elements 16 and 18 relative to each other. In this position, the distance between the first raised annular flange 22 in the first connecting element 16 and the second raised annular flange 24 in the second connecting element 18 is sufficient to align these holes with posts located on the slides of a cocked biopsy gun, and therefore enable the biopsy needle 10 to be loaded into a biopsy gun without manipulation of the connecting elements 16 and 18. The tip of the inner needle 12 is exposed to facilitate insertion of the biopsy needle 10 into the tissue being sampled.

The biopsy needle 10 including the integrated spacer 20 can be inserted into a biopsy gun either in the cocked or uncocked position to accommodate the user's preference. The integrated spacer 20 also facilitates removal of the biopsy needle 10 from a biopsy gun without the necessity to reattach a spacer clip as is required with conventional biopsy needles. If the biopsy needle 10 is inserted while the gun is uncocked, the gun should be cocked prior to use. Insertion of the biopsy needle 10 into a biopsy gun 60 is generally straight forward as shown in Fig. 5. The body of the needle holder 8 is grasped by the user and placed over the interior chamber of the biopsy gun 60, as illustrated in Fig. 5. Vertically extending bore 23 of the first and second connecting elements 16 and 18 are aligned over slides 62 of the biopsy gun 60 and receive posts 64. Without having to remove the integrated spacer 20, the lid to the biopsy gun 60 is closed and is ready for use.

The tip of the biopsy needle 10 is inserted into the tissue to be sampled. The biopsy

PUBLICATION



Nombre de pages...25

BD/AB.....1.....

BD/AB.....

DE.....3.....

CL.....15.....

DR.....22.....

SR...../.....

SR.....

Contrôlé par..... Scanné par.....

Nb de copies..... Article 20.....

ting element 18 along with the integrated spacer
ting element 16 is held stationary. This action is
t of the guiding needle holder 8 wherein flange 24
ole 26 while flange 22 of the first connecting
spacer 20 in slot 28. This movement causes the
ssue being sampled and exposes the recess 13 in
ie to be sampled. The second slide of the biopsy
with the first connecting element 16 forward. This
forward over the recess 13 which causes the outer
e recess 13 and secure it therein. The biopsy
ion illustrated in Fig. 1a. The biopsy needle 10
ed. The integrated spacer 20 in engagement with

the first and second connecting elements 16 and 18 during operation of the biopsy gun 60, stabilizes the first and second connecting elements 16 and 18 and prevents twisting and bending in the biopsy gun 60.

Multiple samples can be taken at the same biopsy site by either reusing the biopsy
5 needle 10 or replacing the inner needle 12. The inner needle 12 is replaced by removing the second connecting element 18 from the integrated spacer 20, sliding the inner needle 12 out of the outer needle 14, and inserting another inner needle into the outer needle 14 and reattaching the second connecting element 18 in the manner previously described. The second connecting element 18 can either be reused or replaced.

10 An alternative embodiment of the invention is shown in Figs. 4a and 4b. In this embodiment the biopsy needle 10A includes an inner needle 42, an outer needle 44, and a guiding needle holder 40. The guiding needle holder 40 comprises an integrated spacer 48 and a connecting element 50. Connecting element 50 is identical to connecting element 16 previously described. The integrated spacer is substantially identical to integrated holder 20,
15 except that longitudinally extending groove 31, longitudinally extending wall 30 and longitudinally extending curved wall 39 do not extend as far in the body of the spacer 20. The proximal end of the spacer 48 is solid for ease of manufacturing and includes a vertically extending bore 41. An inner needle 42 is fixedly attached to the integrated spacer 48 near the proximal end, and the outer needle 44 is fixedly attached to the connecting element 50. The
20 connecting element 50 can be attached to the integrated spacer 48 in the manner previously described herewith for attaching the first connecting element 16 in the previous embodiment.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is

intended that the specification and examples be considered as exemplary only, with the true scope and spirit of the invention being indicated by the following claims.

We claim:

1. A biopsy needle comprising:
 - 2 a guiding needle holder;
an inner needle having a recess in a vicinity of a distal end thereof for receiving a
4 tissue sample, and a proximal end fixedly connected to said guiding needle holder such that
said inner needle does not move relative to said guiding needle holder; and
6 an outer needle substantially coaxial with said inner needle and disposed about a
portion of said inner needle having a proximal end displaceably connected to said guiding
8 needle holder such that said outer needle moves longitudinally relative to said guiding needle
holder.
2. A biopsy needle as claimed in claim 1, wherein said guiding needle holder comprises:
 - 2 an integrated spacer;
a first connecting element displaceably attached to said integrated spacer and movable
4 therein, wherein said outer needle is connected to the first connecting element; and
a second connecting element fixedly connected to said integrated spacer such that said
6 second connecting element does not move relative to said integrated spacer, wherein said
inner needle is fixedly attached to the second connecting element.
3. A biopsy needle as claimed in claim 2, wherein said integrated spacer includes
 - 2 a hole and a slot;
said first connecting element includes a first annular flange displaceably engaged to
4 the slot of the integrated spacer; and

6 said second connecting element includes a second annular flange fixedly engaged to the hole of said integrated spacer.

4. A biopsy needle as claimed in claim 3, wherein said first connecting element is
2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient to enable operation of said biopsy needle in a biopsy gun.

5. A biopsy needle as claimed in claim 4, wherein said first connecting element is
2 positioned along the length of the slot of said integrated spacer a predetermined distance to enable insertion of said biopsy needle in a biopsy gun.

6. A biopsy needle as claimed in claim 5, wherein
2 said integrated spacer having an interior section including a longitudinally extending groove, a curved wall, and an angled wall;
4 said first connecting element includes a first protruding section engaged to the groove of said integrated spacer, a first curved portion that fits in the curved wall of said integrated
6 spacer; and

8 said second connecting element includes a second protruding section engaged to the groove of said integrated spacer, and a second curved portion engaged to the curved wall of said integrated spacer.

7. A biopsy needle as claimed in claim 1, wherein said guiding needle holder comprises:
2 an integrated spacer wherein said inner needle is fixedly connected to the integrated spacer such that said inner needle does not move relative to said integrated spacer; and

- 4 a connecting element displaceably connected to said integrated spacer movable
therein wherein said outer needle is fixedly connected to the connecting element.
8. A biopsy needle as claimed in claim 7, wherein
- 2 said integrated spacer includes a first hole and a slot;
 said connecting element includes an annular flange displaceably connected in the slot
- 4 of said integrated spacer.
9. A biopsy needle as claimed in claim 8, wherein the connecting element is
- 2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient
to enable insertion of said biopsy needle into a biopsy gun.
10. A biopsy needle as claimed in claim 9, wherein
- 2 said integrated spacer includes a longitudinally extending groove, a curved wall, and
an angled wall; and
- 4 said connecting element includes a protruding section engaged to the groove of said
integrated spacer, a curved portion that fits in the curved wall of said integrated spacer, and a
- 6 flat portion.
11. A needle holder for guiding a biopsy needle, comprising:
- 2 an integrated spacer;
 a first connecting element fixedly connected to said integrated spacer; and

4 a second connecting element displaceably connected to said integrated spacer such
that said second connecting element is longitudinally displaceably along said integrated
6 spacer.

12. A guiding needle holder as claimed in claim 11, wherein
2 said integrated spacer includes a hole and a slot;
 said first connecting element includes a first annular flange connected in the slot of
4 the integrated spacer such that it is displaceable relative to said integrated spacer; and
 said second connecting element includes a second annular flange fixedly connected to
6 the first hole in said integrated spacer.

13. A guiding needle holder as claimed in claim 12, wherein the second connecting
2 element is displaceably guided along the length of the slot of said integrated spacer a distance
sufficient to enable insertion of a biopsy needle into a biopsy gun.

14. A guiding needle holder as claimed in claim 13, wherein
2 said integrated spacer includes a longitudinally extending groove, a curved wall, and
an angled wall;
4 said first connecting element includes a first protruding section that fits in the groove
of said integrated spacer, a first curved portion that fits in the curved wall of said integrated
6 spacer, a first flat portion, and a first longitudinal bore; and
 said second connecting element includes a second protruding section that fits in the
8 groove of said integrated spacer, a second curved portion that fits in the curved wall of said
integrated spacer, a second flat portion and a second longitudinal bore.

15. A needle holder for guiding a biopsy needle comprising:
- 2 an integrated spacer; and
- a connecting element displaceably attached to said integrated spacer.
16. A guiding needle holder as claimed in claim 15, wherein the integrated spacer
- 2 includes
- a first hole and a slot; and
- 4 said connecting element includes a raised hole displaceably connected in the slot in
- said integrated spacer.
17. A guiding needle holder as claimed in claim 16, wherein said connecting element is
- 2 displaceably guided along the length of the slot of said integrated spacer a distance sufficient
- to enable insertion of a biopsy needle into a biopsy gun.
18. A guiding needle holder as claimed in claim 17, wherein,
- 2 said integrated spacer includes a longitudinally extending groove, a curved wall, an
- angled wall, and a first longitudinal bore; and
- 4 said connecting element includes a protruding section that fits in the groove of said
- integrated spacer, a curved portion that fits in the curved wall of said integrated spacer, a flat
- 6 portion, and a second longitudinal bore.
19. A biopsy instrument for use in a biopsy gun comprising:
- 2 a hollow outer needle;

an inner needle extending through said hollow outer needle, wherein said inner needle
4 includes a recess near the distal end thereof, said inner needle and said outer needle movable
relative to each other permitting selective encapsulation of said recess on said inner needle by
6 said outer needle;

a first connecting element attached to a proximal end of said outer needle

8 a second connecting element attached to a proximal end of said inner needle and
positioned in the same plane as said first connecting element; and

10 an integrated spacer having an interior section, said first and second connecting
elements engaged to said interior section, and moveable therein relative to each other
12 between a spaced apart orientation and an adjacent orientation whereby said inner needle is
selectively moved between positions exposing the recess of said inner needle and
14 encapsulating the recess of said inner needle when said integrated spacer is positioned within
a biopsy gun.

20. A biopsy instrument for use in a biopsy gun comprising:

2 a hollow outer needle;

an inner needle extending through said hollow outer needle, wherein said inner needle
4 includes a recess near the distal end thereof, said inner needle and said outer needle movable
relative to each other permitting selective encapsulation of said recess on said inner needle by
6 said outer needle;

a connecting element attached to a proximal end of said outer needle; and

8 an integrated spacer attached to a proximal end of said inner needle, said connecting
element engaged to said integrated spacer for relative movement therein whereby said inner
10 needle is selectively moved between positions exposing the recess of said inner needle and

encapsulating the recess of said inner needle when said biopsy instrument is contained within
12 a biopsy gun.

FIG. 1a

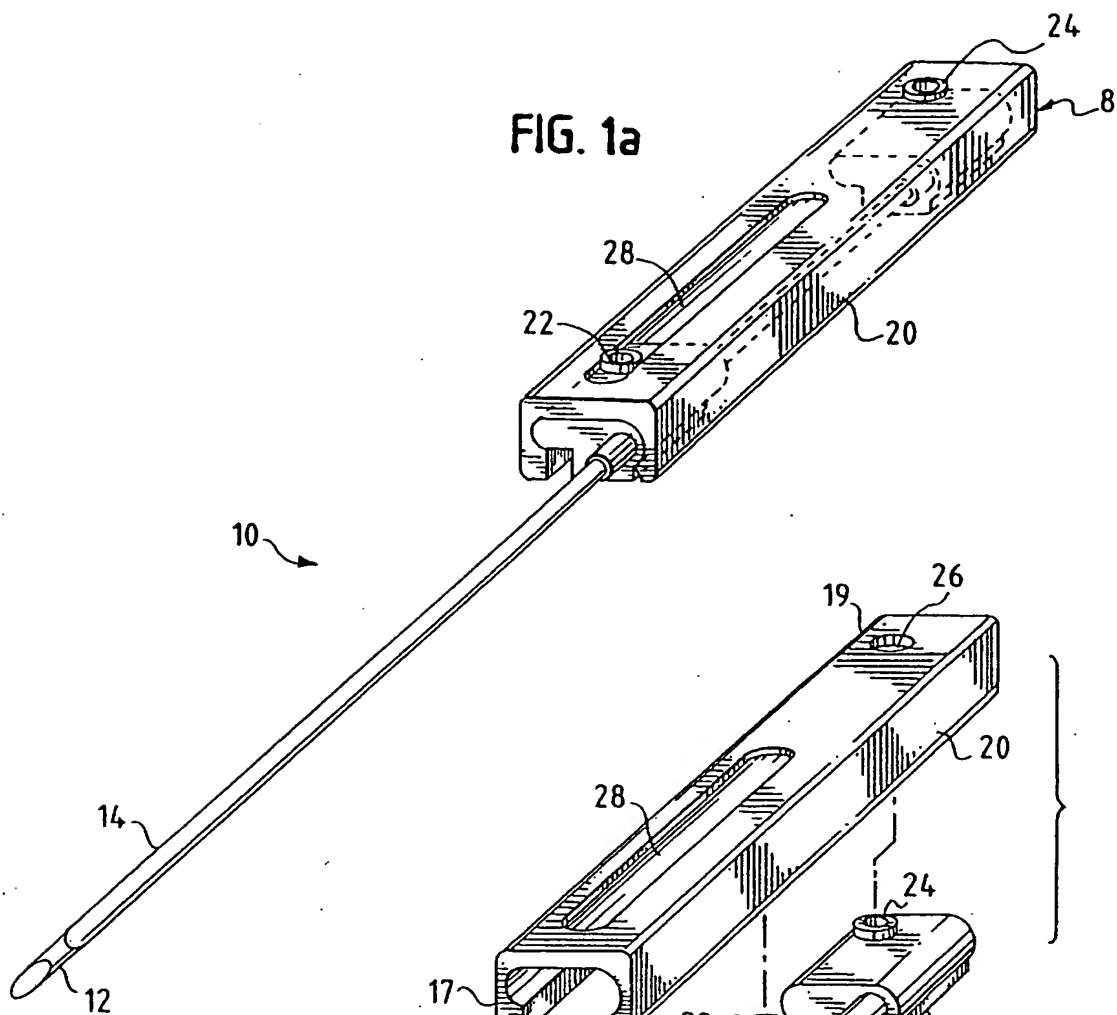
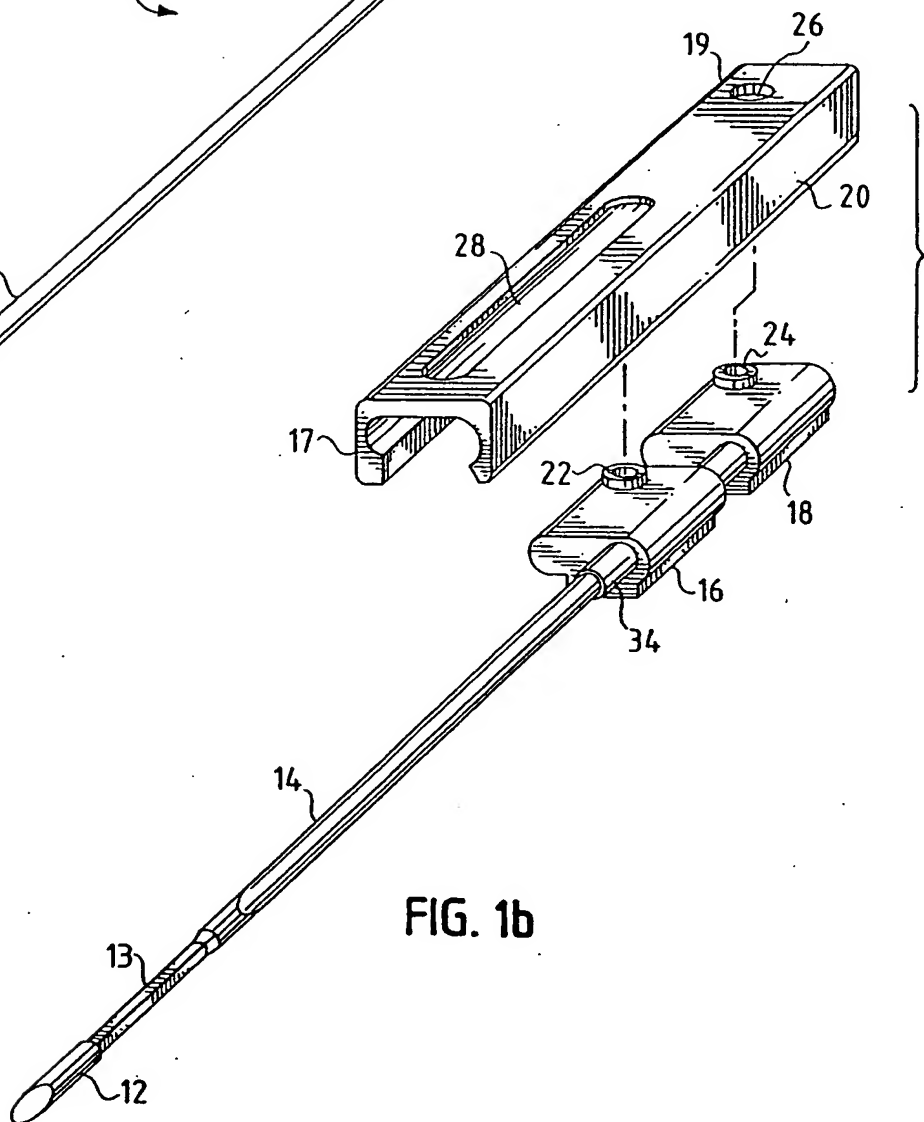


FIG. 1b



2/4
FIG. 2a

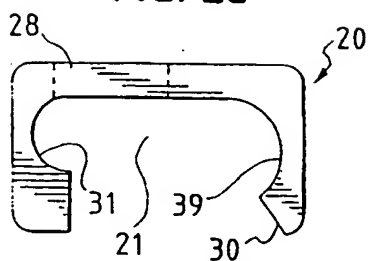


FIG. 2b

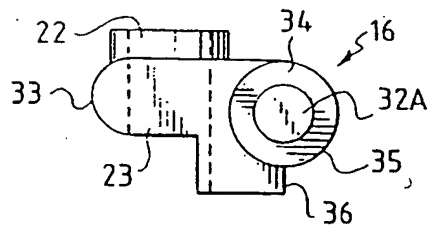


FIG. 3a

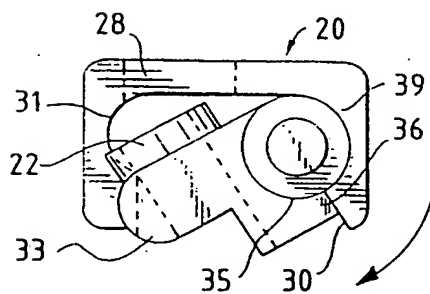
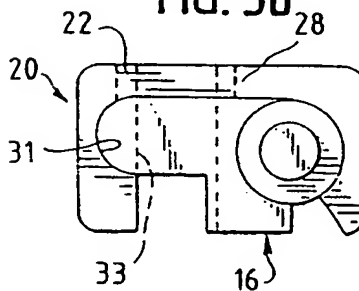


FIG. 3b



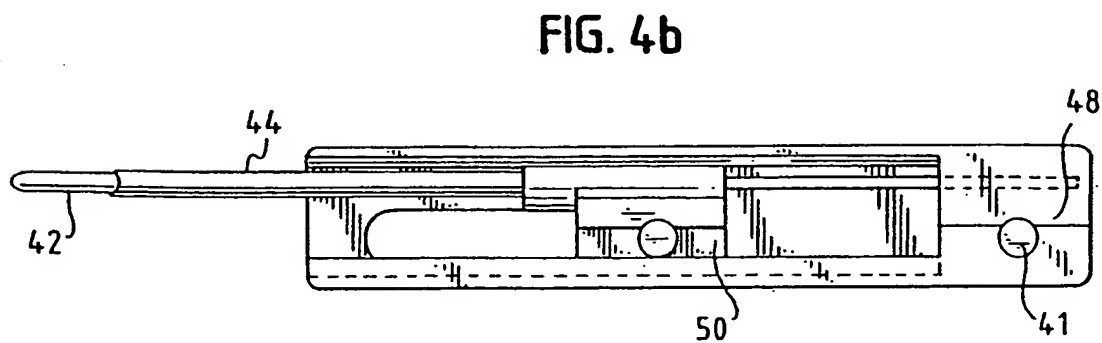
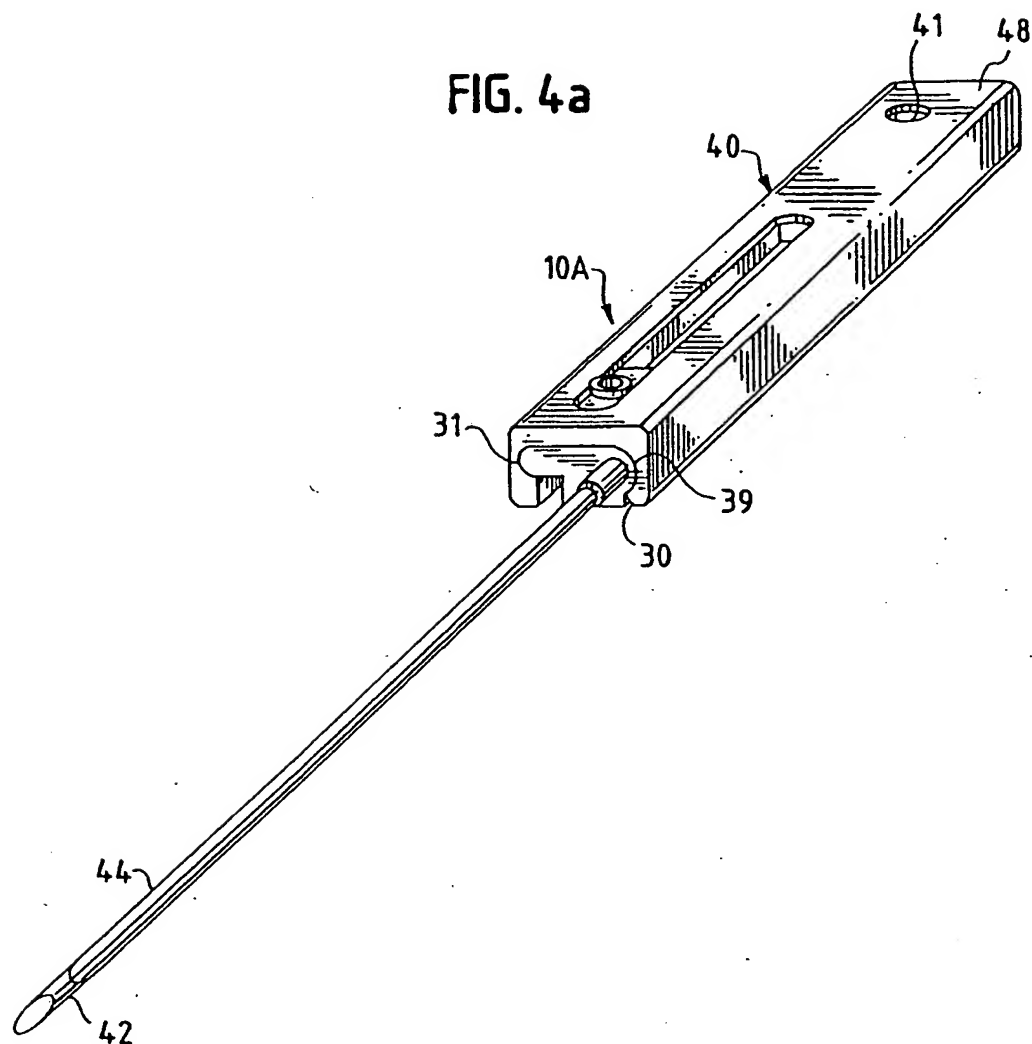
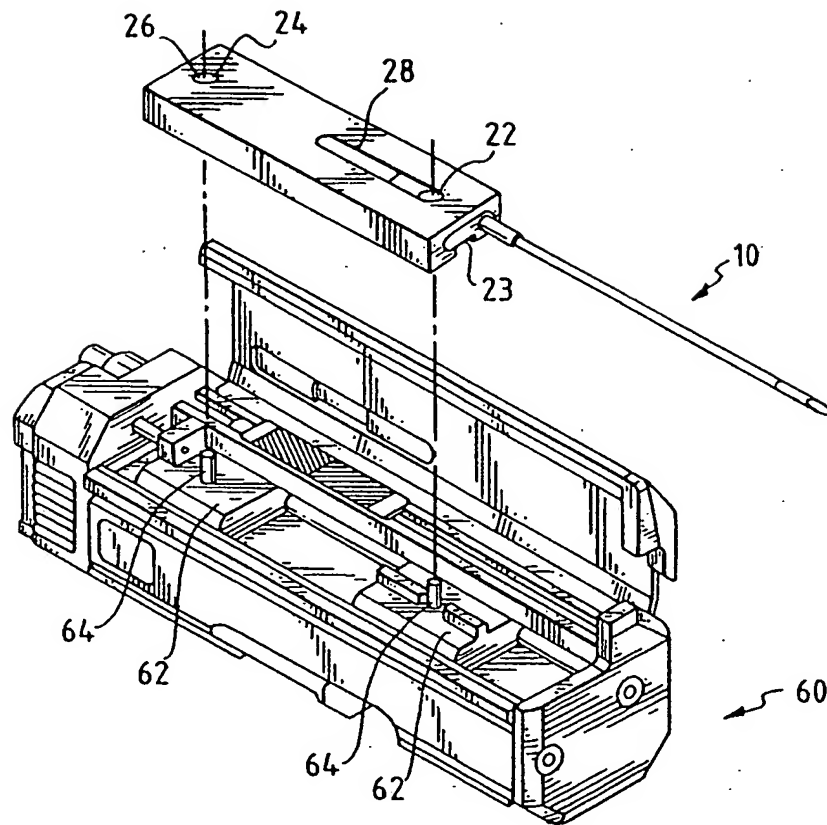


FIG. 5



INTERNATIONAL SEARCH REPORT

Application No

PCT/IB 99/02131

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 316 013 A (STRIEBEL II ROBERT L ET AL) 31 May 1994 (1994-05-31) abstract; figures 2,7A	1,11,15, 19,21
A	US 5 546 957 A (HESKE NORBERT) 20 August 1996 (1996-08-20) abstract; figures 3,4 column 4, line 12-38	1-21
A	US 5 092 870 A (MITTERMEIER ANTON) 3 March 1992 (1992-03-03) abstract; figures 3,10	1-21
A	US 5 163 947 A (KVALO MICHAEL L ET AL) 17 November 1992 (1992-11-17) abstract; figures 5-7	1-21
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

21 December 2000

Date of mailing of the international search report

03/01/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Jonsson, P.O.

INTERNATIONAL SEARCH REPORT

International Application No.
P B 99/02131

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 279 570 A (DOMBROWSKI MITCHELL P ET AL) 18 January 1994 (1994-01-18) abstract; figure 2 . -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No
PCT/IB 99/02131

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5316013 A	31-05-1994	NONE	
US 5546957 A	20-08-1996	DE 9414727 U DE 9414728 U	08-12-1994 08-12-1994
US 5092870 A	03-03-1992	NONE	
US 5163947 A	17-11-1992	NONE	
US 5279570 A	18-01-1994	NONE	

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.